

National Cancer Institute
Institutional Review Board

AGENDA

July 27, 2015

1:00 – 5:00 pm

10 CRC/3-1608

- 1. Review of Draft Minutes, July 13, 2015**
- 2. Announcements**
- 3. Old Business/New Business**
- 4. Problem Report Forms**
- 5. Other Expedited Actions**
- 6. Continuing Reviews**
- 7. Response to Stips** 13C0193-G, "Evaluation of 68Gallium- DOTATATE PET/CT for Detecting Primary and Metastatic Neuroendocrine Tumors" - Electron Kebebew, PI
- 8. Amendment** 15C0145-A, "Phase I/II Study of the Anti-programmed Death Ligand-1 Antibody (a PD-L1 inhibitor) MEDI4736 in Combination with Olaparib or Cediranib for Advanced Solid Tumors and Recurrent Ovarian Cancer" - Jung-Min Lee, PI
- 9. Amendment** 12C0191-F, "Phase II Open Label Non-Randomized Single Agent Study of the SMAC (Second Mitochondrial-Derived Activator of Caspases)-Mimetic Birinapant (TL32711; NSC 756502) in Relapsed Platinum Resistant or Refractory Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer" - Christina Annunziata, PI
- 10. Amendment** 12C0148-B, "SARC016: Phase 2 Study of the mTOR Inhibitor Everolimus in Combination with Bevacizumab in Patients with Sporadic and Neurofibromatosis Type 1 (NF1) Related Refractory Malignant Peripheral Nerve Sheath Tumors" - Brigitte Widemann, PI
- 11. Amendment** 09C0005-P, "Randomized Trial of Cladribine (CdA) with Simultaneous or Delayed Rituximab to Eliminate Hairy Cell Leukemia Minimal Residual Disease" - Robert Kreitman, PI
- 12. Initial Review** P152324, "Phase II Randomized, Placebo-Controlled Trial of PROSTVAC (PSA-TRICOM) in Patients with Clinically Localized Prostate Cancer Undergoing Active Surveillance" - Peter Pinto, PI
- 13. Initial Review** P152299, "Development and Validation of Patient Reported Outcome (PRO) Measures for Individuals with Neurofibromatosis 1 (NF1) and Plexiform Neurofibromas (PNs)" - Pamela Wolters, PI